REMARKS/ARGUMENTS

Independent claim 1 has been amended to specify that the liquid food product contains particles of dehydrated lactic acid bacteria chosen from lactobacilli and bifidobacteria coated with at least one vegetable fat that is solid at ambient temperature, wherein said coated particles of lactic acid bacteria are in the form of granules having an average size of less than 200 μm, wherein said vegetable fats are chosen from hydrogenated and nonhydrogenated, fractionated or unfractionated, esterified or nonesterified substances, food waxes, fatty acids, palm oils with an Mp of 45°C and 58°C, cocoa butter, peanut butter, palm kernel oil, carnauba wax with an Mp = 80-85°C, microcrystalline wax of petroleum origin, palmitic acid, and mixtures thereof, said vegetable fats having a melting point above 40°C, containing lactic acid bacteria in an amount greater than or equal to 1×10^{10} CFU per gram of granules, wherein said granules are free of starch, and wherein said food product has a pH of less than or equal to 4.5 and a water content by weight of at least 83%. These modifications find support throughout the content of claims 2, 6 and 13 to 15. Claims 2, 6 and 13 to 15 have been cancelled; the other claims have been renumbered and their dependency adapted.

The expression "*is greater than or equal to 1×10^{10} CFU per gram of granules, and a maximum of 5×10^{11} CFU per gram of granules*" in claim 16 is replaced by the expression "*is between 1×10^{10} CFU per gram of granules and 5×10^{11} CFU per gram of granules*", both expression having obviously the same scope.

The expression "*finished product*" in claims 19, 21 and 22 is replaced by "*said food product*"; it appears clearly in the specification (for example at page 8, lines 13-16 of the PCT application as published) that the finished product is equivalent to the liquid food product.

The above amendments should overcome the objections raised against previous claims 2, 3, 16, 19, 21 and 22.

Regarding objection raised against claim 8, please find enclosed a copy of the CNCM depositary certificate of filing of strain I-1518. The CNCM is an international depositary authority under the Budapest Treaty. This clearly establishes that the I-1518 strain has been

deposited under the Budapest treaty and the strain is made readily available to the public.

Turning now to the cited prior art, **R1** (US 5,292,657) discloses a rotary disc process for preparing microspheres of freeze-dried microorganisms entrapped in a fatty acid matrix capable of maintaining bacterial activity in acidic environment (stomach).

The main differences between **R1** and the present invention reside in the fact that **R1** does not disclose a liquid food product with a pH of 4.5 or less and a water content of at least 83%; instead **R1** describes the preparation of dried microspheres of bacteria for animal feed rations (see column 2, lines 18-20).

R2 (US 6,447,823) describes a liquid yogurt containing lactic acid bacteria encapsulated using a mixture of hardened oil and of starch; the size of the capsules thus obtained is larger (1 to 3 mm) than granules of the present invention.

The technical problem at the basis of the present invention was to find a solution allowing the encapsulation of microorganisms that maintains said microorganisms viable in a low pH (4.5 or less) and highly aqueous (water content of at least 83%) environment.

As already mentioned, the purpose of **R1** is the preparation of freeze-dried microorganisms entrapped in a fatty acid matrix capable of maintaining bacterial activity in acidic environment. Such entrapped freeze-dried microorganisms are obtained with very specific equipment, and it is therefore explained in **R1** that "*it is important to note that rotary disc microsphere processing provides* ***a distinctly different product*** *than does conventional tower spray drying*" (column 3, lines 53-56).

The preferred embodiment of **R1** (column 4, lines 1-10) is performed when the following conditions are met during the process:

1 The fatty acid is stearic acid;

2 The microorganism is *Enterococcus faecium*;

3 The slurry of bacteria and fatty acids contains 35% bacteria and 65% stearic acid.

4 The rotary disc is a four inch disc;

5 The speed of the rotary disc is 3000 rpm and

6 The feed rate is 100 g/min.

In such specific conditions, the particles size is between 75 μm and 300 μm, preferably

below 250 μm; nowhere else in **R1** the particle size is given. Microspheres of **R1** are then mixed in a dry feed product.

Differences between the object of claim 1 and **R1** lay in the fact that **R1** uses a different process which influences the physical properties of the product (see column 3, lines 53-56 of **R1**) and thus, the particles size.

Knowing this, the skilled person would not have tried to perform the process of **R1** with different conditions than those above-described: **different microorganisms** (lactobacilli and bifidobacteria vs. *Enterococcus faecium)* and **different fats** (fats with a melting temperature above 40°C vs. stearic acid which has a melting point of 35°C) for preparing granules having an average size of less than 200 μm.

Furthermore, the preparation of a dispersion of microspheres in a **liquid** food product and the taste of these microspheres are not problems that need to be addressed in **R1**; for this additional reason, the teaching of **R1** is not relevant for the skilled man.

Because, **R1** does not allow the skilled person to prepare granules of microorganisms **which are small enough** so as to be acceptable from an organoleptic point of view (no feeling grains of sand on the palate when eating the liquid food product) and in which the survival of these microorganims is significantly increased when mixed with low pH and high aqueous product, there is no reason for the skilled person to combine the teachings of **R1** and **R2**.

For these reasons, the pending claims are not obvious over the teaching of **R1** in view of **R2**.

Information Disclosure Statement

In an accompanying supplemental Information Disclosure Statement, we have submitted the English translation of two prior art documents which were newly cited in the Japanese examination:

Reference 1 corresponds to Japanese Patent Application **JP 4-82827** from Snow Brand Milk Product Co Ltd and published on March 16, 1992. **Reference 1** discloses entero-soluble capsules comprising bifidobacteria coated with oil having a melting temperature exceeding body temperature; these capsules are intended to be used in acidic beverage or yogurts. **Reference 1**

discloses a range of particles' size distribution of 30 - 2000 μm, preferably 50 - 10000 μm. The upper range is much higher than the range of claim 1.

In embodiment 2 and 3, particle sizes of 200 and 100 μm are disclosed, but here the bacteria are added in the form of a liquid, not in freeze dried form.

In embodiment 1, 6 and 7, the bifidobacteria are added in dry form. Notably the particle size is much higher when the bifidobacteria are added in dry form, namely 40-600 μm, 300 μm and 100-450 μm, respectively.

On the contrary in the present invention the lactic acid bacteria are added as freeze dried bacteria and a small, desired, particle size of the capsules is obtained. A small particle size is crucial for purposes of distribution/dispersion stability in liquid food products and taste effect.

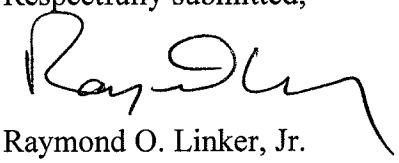
Reference 2 corresponds to Japanese Patent Application **JP 60-141281** from Meiji Milk Product Co Ltd published on July 26, 1985. **Reference 2** describes a manufacturing method for preparing dried lactic bacteria granules having good handleability and preservability using a spray drying process and a lyoprotectant. Granules are obtained by mixing bacteria with a coagulation salt solution containing sodium or potassium alginates. This process leads to large granules: larger than 0.5 mm (mesh 24-32).

In view of the foregoing, it is submitted that the claims as now presented patentably distinguish over the prior art of record. Favorable reconsideration by the Examiner and formal notification of the allowability of all claims are solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any required fee

(including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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TRAITE DE BUDAPEST SUR LA RECONNAISSANCE
INTERNATIONALE DU DEPOT DES MICRO-ORGANISMES
AUX FINS DE LA PROCEDURE EN MATIERE DE BREVETS

FORMULE INTERNATIONALE

DESTINATAIRE :

CIRDC
15, avenue Galilée
92350 LE PLESSIS-ROBINSON

RECEPISSE EN CAS DE DEPOT INITIAL, délivré en vertu de la règle 7.1 par l'AUTORITE DE DEPOT INTERNATIONALE identifiée au bas de cette page

NOM ET ADRESSE DU DEPOSANT

I. IDENTIFICATION DU MICRO-ORGANISME

Référence d'identification donnée par le DEPOSANT :	Numéro d'ordre attribué par l'AUTORITE DE DEPOT INTERNATIONALE :
DN-114 001	I - 1518

II. DESCRIPTION SCIENTIFIQUE ET/OU DESIGNATION TAXONOMIQUE PROPOSEE

Le micro-organisme identifié sous chiffre I était accompagné :

☐ d'une description scientifique

☐ d'une désignation taxonomique proposée

(Cocher ce qui convient)

III. RECEPTION ET ACCEPTATION

La présente autorité de dépôt internationale accepte le micro-organisme identifié sous chiffre I, qu'elle a reçu le (date du dépôt initial) [1]

IV. RECEPTION D'UNE REQUETE EN CONVERSION

La présente autorité de dépôt internationale a reçu le micro-organisme identifié sous chiffre I le 28 septembre 1994 (date du dépôt initial)
et a reçu une requête en conversion du dépôt initial en dépôt conforme au Traité de Budapest le 30 décembre 1994 (date de réception de la requête en conversion)

V. AUTORITE DE DEPOT INTERNATIONALE

Nom : CNCM
Collection Nationale
de Cultures de Microorganismes

Adresse : INSTITUT PASTEUR
28, Rue du Docteur Roux
F-75724 PARIS CEDEX 15

Signature(s) de la (des) personne(s) compétente(s) pour représenter l'autorité de dépôt internationale ou de l'(des) employé(s) autorisé(s) : Mme Y. CERISIER
Directeur Administratif de la CNCM

Date : Paris, le 06 février 1995

1 En cas d'application de la règle 6.4.d), cette date est la date à laquelle le statut d'autorité de dépôt internationale a été acquis.

Formule BP/4 (page unique)

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